1929 Margaret St.
St. Paul, MN 55119-3921
July 16, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Ln., Rm 1061
Rockville, MD 20857-0003

Re: Docket No. 98N-1265
Sec. 503A, FDA Modernization Act of 1997
Draft Memorandum of Understanding

Greetings:

We write this letter to inform you of our objections to provisions of the Compounding Section 503A of the FDA Modernization Act and of the draft Memorandum of Understanding (MOU) as published by the FDA on January 21, 1999.

Adoption of that MOU would severely restrict our rights as healthcare patients to obtain certain products prescribed for our treatment by our physicians. It would restrict the rights of compounding pharmacists to serve the medical needs of the public. Restricting the providing of compounded drugs to patients living in the same state as the location of the compounding pharmacists would effectively deny the use of necessary drugs to those living in states where there is no compounding pharmacist who would prepare that drug.

A compounded drug was recently prescribed by a physician (MD) of our Health Maintenance Organization in St. Paul, upon recommendation of other medical doctors. We were unable to locate a compounding pharmacist in the State of Minnesota who could fill that prescription, but were able to obtain it from a compounding pharmacist located in neighboring Wisconsin. As we understand the provisions of the proposed MOU, we would be denied access to that pharmacist in the future simply because we do not live in the state where his firm is located. That would effectively deny us the right to use that medicine for that accepted type of treatment.

Please re-consider that provision of the proposed MOU and remove that residency restriction. Thank you.

Sincerely,

Mary E. Kachelmyer

Mary E. Kachelmyer

Clement P. Kachelmyer

98N-1265

C4178

Mr. & Mrs. Clement P. Kachelmyer
1929 Margaret St.
Saint Paul, MN 55119-3921

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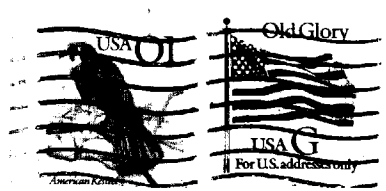

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